CENTER FOR VETERINARY MEDICINE PROGRAM POLICY AND PROCEDURES MANUAL GUIDE 1243,3340

OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWERS' CHAPTER

PLACING STAMP DATES ON THE ELECTRONIC COPIES OF LETTERS ISSUED BY ONADE

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I. PURPOSE

The Document Control Unit (DCU) Stamp Date is also known as the Final Action Date or Letter Issue Date. Because the stamp date is physically applied to the official paper letter after the paper copy has been printed from the final electronic file, a method is needed to ensure that the electronic file is modified to reflect the DCU Stamp Date. The purpose of this guide is to describe the formal procedure for inclusion of the stamp date in the electronic copy of letters to be stored on the R: drive (also known as the CVM Archives or CVM Records Drive) of the Local Area Network.

NOTE: This procedure would apply only to letters resulting from submissions that are routed through STARS. An example of a submission that is not routed through STARS is a Suitability Petition. The stamp date on such documents is not electronically accessible; therefore, an Applications Examiner cannot query/search STARS for the stamp date/final action date.

II. THE STAMP DATE PROCESS FOR ELECTRONIC COPIES

The DCU is generally responsible for physically stamping the date on the official paper copy of letters. An exception to this would be approval letters that are signed by the Center or Office Director. These are stamp dated by HFV-102 on the date of the signature. This "stamp date" is the official date of the letter issued

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to the sponsor, and appears on all paper copies both filed in the official jacket file and distributed within the Agency. This date is also entered into the Center's Submission Tracking and Reporting System (STARS) as the final action date.

Each division is responsible for assuring that the stamp date is added to the electronic files of all letters originating in the division. The process used may vary between divisions. The electronic files must be modified to reflect the stamp date before the files are moved to the division's "Complete Folder" on the S:\drive. The Office Records Administrator is responsible for moving files from the complete folders to the R:\drive.

III. LOCATION OF THE STAMP DATE IN THE ELECTRONIC COPY

The stamp date is placed in the same line as the Submission ID in all letters to be issued, and should be right justified. The information will be in the same font and size as the body of the letter.

Most reviewers find using a one-row, two-column table with the left column containing the Submission ID (left justified), and the right column containing the date in a month, day, year (Month, DD, YYYY) format (right justified) the easiest method for doing this (see example of this method in Section IV).

IV. EXAMPLE

NOTE: Table border (shown below) must be hidden on actual letter.

ANADA 100-999 A-0000	January 01, 2001

<Followed by the Letter>

V. REFERENCES

Standard Operating Procedures for R: drive administration located in R:\Onade_sop directory on the CVM LAN

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